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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,178	02/12/2002	David J. Eyre	7475-69889	5007
49437	7590	01/27/2006	EXAMINER	
ROCHE			SMITH, CAROLYN L	
11 SOUTH MERIDAN STREET			ART UNIT	
INDIANAPOLIS, IN 46204			PAPER NUMBER	

1631

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,178	Applicant(s) EYRE ET AL.	
	Examiner Carolyn L. Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-24 is/are pending in the application.
4a) Of the above claim(s) 24 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18-24 is/are rejected.
7) ☒ Claim(s) 18 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>122005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendments and remarks, filed 11/14/05, are acknowledged. Amended claim 18 is acknowledged.

Applicant's arguments, filed 11/14/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The petition to change inventorship by deleting Carl T. Wittwer, filed 7/28/05, is accepted.

Claims 18-23 are herein under examination. Claim 24 remains withdrawn due to being drawn to non-elected specie.

Claim Objections

Claim 18 is objected to because of the following informalities: Claim 18 contains improper periods on lines 9, 10, and 12. Appropriate correction is required. This objection is necessitated by amendment.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 18, 22, and 23 are rejected under 35 U.S.C. 102(e)(2) and 102(f) as being anticipated by Wittwer (P/N 6,387,621 B1).

This rejection is necessitated by amendment.

Wittwer discloses a system with a rapid thermal cycling device using capillary tubes and hot air temperature control (col. 4, line 66 to col. 5, line 2) which represents the instrument in instant claim 18, 22, and 23. Wittwer discloses analyzing a sample for the presence of a nucleic acid using polymerase chain reaction and a fluorescent detecting entity (col. 1, lines 13-18) as stated in the preamble of instant claim 18. Wittwer discloses amplification with product analysis for “real-time” PCR in the same instrument (col. 1, lines 25-40). Wittwer discloses the LightCycleTM as a rapid temperature cycler with a fluorimeter (col. 5, lines 42-44) which is a PC-based instrument with integrated algorithms in the LightCycleTM platform (col. 5, lines 45-57) which represents a temperature cycler, fluorimeter, and processor, as stated in instant claim 18. Wittwer discloses determining the presence of a nucleic acid by analyzing fluorescent entity measurements capable of detecting the nucleic acid and its number during amplification via slope analysis of fluorescence intensity (col. 2, lines 27-52) and a fluorescent entity providing a

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signal related to the quantity of the nucleic acid (claim 1), as stated in instant claim 18. Witter discloses comparing fluorescent values after each amplification cycle (col. 2, lines 45-52). Wittwer discloses the automated process involving a thermal cycler having a sensor for reporting fluorescence values as a function of cycle number and a processor programmed with an algorithm to process values and report a positive or negative result (col. 2, lines 53-58) wherein values represent scores, reporting as a function of cycle numbers represents a plurality of tests, and a positive result represents the presence of a nucleic acid, as stated in instant claim 18. Wittwer discloses initiation of the analysis algorithm prior to the completion of temperature cycling (col. 2, first paragraph), as stated in instant claim 18. Wittwer discloses using a confidence interval test (col. 8, lines 53-67). Wittwer discloses accounting for background fluorescence and comparing fluorescent values to a baseline fluorescent region (col. 2, lines 45-47). Wittwer discloses sample temperature tests using capillaries with forced air heating allowing precise control of temperature as well as using a rapid temperature cycler with a fluorimeter (col. 5, lines 8-44). Wittwer discloses analysis occurring concurrently with amplification to decrease sample handling, save time, and reduce contamination risks (col. 1, lines 29-38). Wittwer discloses reporting values as a function of cycle number and reporting results (col. 2, lines 53-58) and analyzing fluorescent measurements over a wide range of amplification cycles (col. 6, lines 48-63). Wittwer discloses a maximum to baseline comparison (col. 6, first paragraph). Wittwer discloses determining the test point cycle for determining a positive or negative result which may be the last cycle for a curve not well behaved (col. 8, lines 45-48).

Thus, Wittwer anticipates the limitations of instant claims 18, 22, and 23.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittwer (P/N 6,387,621 B1) as applied to claims 18, 22, and 23 above, and further in view of Schork et al. (P/N 6,291,182 B1).

This rejection is necessitated by amendment.

Wittwer discloses the limitations of instant claims 18, 22, and 23, as set forth in the 35 USC 102 rejection above. Wittwer does not teach all of the plurality of tests as stated in instant claims 19-21.

Schork et al. describe methods, software, and apparatus for determining the presence of a gene with a detectable trait in a genomic region (presence of a nucleic acid in a sample) (abstract). Schork et al. describe using a Perkin Elmer 9600 Thermocycler to perform amplification of nucleic acids (col. 47, lines 1-6). Schork et al. describe performing 40 cycles with 30 seconds at 95 degrees Celsius, 1 minute at 54 degrees Celsius and 30 seconds at 72 degrees Celsius (col. 47, lines 2-6) which represent rapid thermal cycling, as stated in instant claim 22. Schork et al. describe using a fluorimeter and Picogreen (fluorescence) to determine quantities of amplification products (col. 47, lines 7-9). Schork et al. describe excluding artifacts

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due to background noise by comparing two DNA strands (col. 47, lines 29-34) which represents a signal-to-noise ratio test, as stated in instant claim 19. Schork et al. describe using a variety of mathematic analysis tests, including Expectation-Maximization method (Maximum to Baseline Comparison Test) (col. 2, line 6), Wilcoxon rank test (function ordering test) (col. 2, line 62), Kolmogorov-Smirnov test (efficiency test using normal distribution) (col. 2, line 65), chi-square test (confidence interval test) (col. 2, line 50), and nonparametric tests (Last Rise Test) (Fig. 24), as stated in instant claims 20 and 21. Schork et al. describe performing linkage analysis based upon establishing a correlation between transmission of genetic markers and that of a specific trait throughout generations within a family and statistical methods for determination of the likelihood that the marker and trait are segregating independently (col. 18, lines 39-64) which represents a type of Channel Consistency Test where the channel consistency is represented by the consistent flow (presence) or lack thereof of the marker and trait transmission throughout generations, as stated in instant claim 20.

Wittwer and Schork et al. provide methods and devices for determining the presence of a nucleic acid in a sample (abstract of each). Wittwer states there is a need for algorithms for detection, quantification, and genotyping (col. 2, lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to analyze data with detection analysis tests, stated by Schork et al., in the method of Wittwer. A person of ordinary skill in the art would have been motivated to use the plurality of tests presented by Schork et al. in the method of Wittwer, because data processing occurring during amplification and concomitant analysis results can be used to modify temperature cycling and to acquire additional data during

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the latter stages of the amplification procedure to optimize amplification protocol and data quality, as stated by Wittwer (col. 2, lines 8-13).

Thus, Wittwer, in view of Schork et al., make obvious the instant invention.

Applicant's prior art arguments with respect to claims 18-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
1/19/06

January 10, 2006